

**The Secretary's Advisory Committee on
Heritable Disorders in Newborns and Children
(SACHDNC):**

BY-LAWS

Updated 5/16/2012

SACHDNC By-Laws

SECTION I: PURPOSE

The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) provides advice and recommendations to the Secretary about aspects of newborn and childhood screening and technical information for the development of policies and priorities that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders. The Committee also makes recommendations, gives advice, and/or provides information to the Secretary about the grant program established under 42 U.S.C. § 300b-8. Activities carried out under 42 U.S.C. § 300b-12 are undertaken in consultation with the Committee, and activities carried out under 42 U.S.C. § 300b-15 take into consideration the recommendations of the Committee.

The Committee recommendations impact: state-based newborn screening programs, public and private health providers who provide services to individuals with heritable disorders, public health officials and non-governmental organizations that develop newborn and child screening policy, families/parents/consumers, and the public.

SECTION II: AUTHORITY

The Secretary of Health and Human Services (the Secretary, HHS) established SACHDNC, as directed under Section 1111 of the Public Health Service Act, codified at 42 U.S.C. § 300b-10. Its activities are further governed by the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App. 2), and by 41 C.F.R. Parts 101-6 and 102-3, setting forth standards for the establishment, utilization, and management of Federal Advisory committees.

SECTION III: MEMBERSHIP

SACHDNC members are selected based on their expertise and qualifications necessary to contribute to the accomplishments of the Committee's objectives. Through its recommendations regarding newborn and child screening programs, the SACHDNC plays a leading role in the promotion of public health in the United States.

FACA membership policy (FACA § 5(c)) provides that Committee membership be fairly balanced in terms of points of view represented and the Committee's function. The Department gives close attention to the membership of the Committee to ensure that it reflects a distribution of the experience and expertise needed to understand and serve the diversity of the population impacted.

The Committee shall not exceed 15 voting members, including the Chair and Federal Ex-officio members. Voting members are appointed by the Secretary or his/her designee.

SACHDNC By-Laws

Voting members include:

1. Medical, technical, or scientific professionals with special expertise in heritable disorders, or in providing screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders.
2. Individuals, with expertise in ethics and infectious diseases, who have worked and published material in the area of newborn screening.
3. Members of the public having special expertise about or concern with heritable disorders.
4. Administrator* of the Health Resources and Services Administration (HRSA).
5. Director* of the Centers for Disease Control and Prevention (CDC).
6. Director* of the National Institutes of Health (NIH).
7. Director* of the Agency for Healthcare Research and Quality (AHRQ).
8. Commissioner* of the Food and Drug Administration (FDA).

**(or their delegated designee)*

The Committee may also include up to 12 non-voting liaison/organizational representatives who represent organizations with broad constituencies affected, or impacted by, the work of the SACHDNC. Non-voting liaison/organizational representatives are appointed by voting SACHDNC members.

Non-voting liaison/organizational representatives include:

1. Other federal agencies
2. Public health constituencies – State and Local
 - a. Hospitals and medical home
 - b. Professional societies with an emphasis on public health
 - c. Organizations that support state and local public health programs
3. Consumer/family organizations, advocacy groups
4. Primary Care
 - a. Nursing organizations and professional societies (i.e., clinical and scientific)
5. Subspecialty
 - a. Professional societies (i.e., clinical and scientific)
6. At-large – may represent any of the above categories.

APPOINTMENT TERMS

Each voting member serves for a term of 4 years. Voting members may be re-appointed to serve up to an additional 4 years at the discretion of the Secretary.

Each non-voting liaison/organizational representative serves for a term of up to 4 years (except for at-large representatives, who serve for a 2-year term). Non-voting liaison/organizational representatives may reapply at their scheduled term expiration for a renewed term of up to 2 – 4 years.

SECTION IV: MEETING PROCEDURES

Meetings are held at least 2 times a year in the Washington, D.C. metro area and/or virtually via teleconference and webinar.

SACHDNC By-Laws

Meeting dates for the calendar year are announced in advance. Meeting information (e.g., draft agenda items, potential Committee votes, location) is published in the Federal Register and posted on the SACHDNC website as soon as details are available.

Apart from scheduled meetings, the DFO may request members to meet on an urgent or emergency basis by requesting that the Chair establish a “consultation workgroup” consisting of SACHDNC members to discuss the nature of the issue and possible responses to it. The workgroup will report its findings and recommendations to the full Committee for their deliberation.

A quorum – eight (8) of the 15 voting members – is required for the conduct of Committee business.

Except as noted otherwise in these By-Laws, the Chair will use the most current edition of Roberts Rules of Order as a guide when conducting Committee meetings.

A. Agenda

Potential agenda topics for SACHDNC consideration are most often determined by the Committee Chair, in consultation with the DFO and SACHDNC members, as well as by program staff from HRSA, AHRQ, CDC, NIH, and FDA. Additionally, the general public, scientific and medical professional organizations, advocacy groups, or manufacturers of technologies, tests, or processes for screening may also suggest topics.

All Committee members will be notified of draft agenda items, including potential votes, in advance of Committee meetings.

B. Meeting Transparency

Meetings are open to the public for their entire duration. If, during the course of an open meeting, matters inappropriate for public disclosure arise, the DFO will order such discussions to cease and will schedule a closed session.

Meetings will be closed only in limited circumstances and in accordance with applicable law. In addition, requests for closed meetings must be approved by HRSA's Office of General Counsel (OGC) 30 days in advance of the session. All provisions of the FACA and Government in the Sunshine Act (GISA) regarding closed sessions will be followed. Where the DFO has determined, in advance, that discussions during a Committee meeting will involve matters about which public disclosure would be harmful to the interests of the government, industry, or others, an advance notice of a closed meeting, citing the applicable exemptions of the GISA, will be published in the Federal Register. The notice may announce the closing of all or just part of a meeting.

C. Public Comments

Requests to make oral public comments on specific agenda items should be requested in advance when registering to attend the meeting. Members of the public who wish to address

SACHDNC By-Laws

the Committee can also contact the DFO to request public comment time. In the event of a large volume of requests, the time allowed to accommodate everyone may be limited.

Written public comments on specific agenda items may be submitted to the Committee as an alternative to making oral comments, but are not read aloud during the meeting. Written comments should be concise in order to facilitate the Committee's ability to properly review and consider all comments received.

D. Minutes, Transcripts and Document Records

All documents, reports, or other materials prepared by or for the Committee constitute official government records and are maintained according to FACA and HHS records management policies and procedures.

The meeting minutes include a record of the persons present (including the names of Committee members, names of staff, and the names of members of the public from whom written or oral presentations were made), a summary of the matters discussed, conclusions reached, and voting details, as well as submitted written public comments.

Minutes and detailed transcripts of open meetings, votes, presentations, reports, and submitted written public comments will be posted on the SACHDNC website. Minutes of closed meetings are subject to the withholding of matters about which public disclosure would be harmful to the interests of the government, industry, or others, and which are exempt from disclosure under the Freedom of Information Act (FOIA). Requests for minutes of closed meetings must be submitted through a FOIA request to HRSA.

SECTION V: VOTING

Voting members are specified by the Charter. (Details can also be found in Section III – Membership)

All votes are required to be scheduled in advance of the Committee meeting.

A quorum – eight (8) of the 15 voting members – is required for the conduct of Committee business, including voting. In order for a vote to occur, a majority of members in attendance and not abstaining from voting is required. In the absence of a majority of members in attendance and not abstaining from voting, a vote cannot take place. An abstention is not a vote. It is a refusal or a refrain from voting and will not be counted to determine the majority needed for the vote to occur.

All voting actions, including abstentions, will be documented and individually identified.

Federal Ex-officio votes represent the position of the Federal Agency, not the independent position of the individual representing the Federal Agency.

Proxy voting is not allowed. However, Federal Ex-officio members are permitted to send designees who have been delegated the authority by the principal (Administrator of HRSA,

SACHDNC By-Laws

Directors of NIH, CDC, AHRQ or Commissioner of FDA) to participate in discussions and/or voting.

Letters/statements from absent voting members presenting a position on a particular matter under consideration by the Committee shall not constitute a vote on the matter, but may be read to the Committee by the Chair. Letters/statements will be appended to the minutes of the Committee.

All members, including Federal Ex-officio members, are expected to announce any conflicts of interest, as described within Federal law (18 U.S.C. §208) prior to any voting.

SECTION VI: ROLE OF COMMITTEE CHAIR AND DESIGNATED FEDERAL OFFICER

Committee Chair: The Chair leads all proceedings, duties, and activities of the Committee. The Chair is also the spokesperson. The Chair works with the DFO to establish priorities within the purview of the Committee.

Designated Federal Officer: The DFO serves as the government's agent for all matters related to the management of the SACHDNC's activities, and ensures all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives. The DFO will consult with Federal Ex-officio members regarding meeting agendas and will inform them of potential votes in advance of Committee meetings.

SECTION VII: EXPENSES AND REIMBURSEMENT

Expenses related to the operation of the SACHDNC will be borne by the Health Resources and Services Administration. Expenditures of any kind must be approved in advance by the DFO.